Medical Device Regulatory Requirements

Malaysia

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Executive Summary: Malaysia is one of the fastest growing medical device markets in Southeast Asia. A voluntary registration system for medical device companies was launched in 2006, in preparation for a more extensive medical device regulatory regime. A wide-ranging Medical Device Act has been under development for several years, but implanting provisions of the Act have not been released to the public as of September 2008. The new Act is expected to impact significant portions of the medical device market, including the device registration process, packaging requirements, and also require suppliers not based in Malaysia to have a local representative. As of September 2008, the only regulated device categories are refurbished medical devices (which may not be purchased with public money in Malaysia), and devices which emit radiation, which must be examined by the Malaysian government before being sold to healthcare institutions.

Regulating Agencies: Malaysia has two regulatory bodies for medical devices: The Medical Device Bureau, and the Atomic Energy Licensing Board of the Malaysian Ministry of Science, Technology, and Innovation. The Medical Device Bureau administers the Voluntary Registration of Medical Devices Establishments (MeDVER) program, which will likely become mandatory under the Medical Device Act. The licensing board exclusively regulates medical devices which emit radiation.

Laws and Regulations: In August 2007, Malaysia issued a draft Medical Device Act which indicated an intention to follow Global Harmonization Task Force guidance documents. However, the issuance of implementing regulations will determine whether adherence to the Act will be easy or problematic for medical device importers. This report will be updated once new information is available.

Definition of Medical Devices: The Medical Device Bureau of Malaysia considers a medical device to be "all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability". Different classes of medical device will be established for regulatory purposes under the proposed Medical Device Act.

General Market Overview: Malaysia is a moderately sized, but fast growing, market for medical equipment. The current market size is $585 million, according to the Malaysian government, and is expected to grow 22% to $717 million by 2011. The U.S. Commercial Service estimates the market to already be even larger in size, at $1.2 billion. While Malaysia does manufacture a number of rubber based medical products, 90% of its medical devices are imported. Of this, the U.S. has the largest

market share (26%). As Malaysia continues to develop, a larger number of patients and increased investments to provide quality health care should increase demand for medical devices.

The Malaysian Ministry of Health manages the national healthcare program which is responsible for roughly 90% of the health expenditures in Malaysia. The Malaysian healthcare program offers whatever services Malaysian citizens need for a small co-pay in public facilities. A newer system, the National Health Insurance Scheme (NHIS) has been in the works since 2002, but no progress towards implementation has occurred to date. The NHIS would theoretically create a universal insurance scheme in which all citizens are required to contribute towards a fixed operating budget. A limited private system operates concurrently, which is primarily used by affluent Malaysian individuals and a number of medical tourists from less developed countries in the region.

Malaysia is currently the leading supplier of many categories of rubber-based products, including gloves and catheters. Plans exist to expand production into additional areas, including Combination Products, Home/Self Care Products, In-Vitro Diagnostics, Cardiovascular Devices, Orthopaedic Devices, and medical/surgical devices and instruments. Imported high technology is also in demand, which is not manufactured in Malaysia as of the date of this report.

Registration Procedures: Devices emitting radiation are restricted, and any such device must be examined by the Ministry of Health before it can be used in Malaysia. Permits for radiation emitting devices can be obtained through the Atomic Energy Licensing Board of the Malaysian Ministry of Science, Technology, and Innovation: http://www.aelb.gov.my/aelb/engv/text/engindex.asp

The Tendering Process: There are different tendering procedures in Malaysia, depending on the size of the contract. Hospitals or public institutions may directly acquire products below a threshold of 50,000 RM ($15,300 U.S.); products above 50,000 RM require quotations from at least five suppliers. For tenders over 200,000RM ($61,300 U.S.), companies must register with the Ministry of Health. Tenders will only be solicited from international corporations in the case that local businesses are unavailable to provide the needed supplies, regardless of tendering level[i]. Preferential treatment is given to Malaysian businesses for tenders below RM 10,000,000 if they include at least 10% locally produced goods. Tender offers for higher amounts also receive preferential treatment if the bid contains locally produced supplies and labor, although the qualifying percentage is lower[ii].

Companies successful in the tendering process are selected, not just by the lowest bid, but also on other criteria such as the stability of the bidding company[iii]. It is very important to possess a local presence in Malaysia to stay abreast of information on tenders and maintain strong business relationships with local governments and businesses which can provide access to the national government.

Tendering in Malaysia has up to ten primary steps[iv]: 1. Project determination – An agency identifying a need for work or a product. 2. Project Specification – Specification of cost and how tendering will take place. 3. Preparation of Documentation – Provides expectations, scope of project, information for bidders, etc. 4. Tender Evaluation – Consideration of the bids submitted. 5. Presentation of Tender Briefs – Briefs presented to relevant governmental tender board. 6. Approval by Tender Board – Unconditional or Conditional approval by board of a bid which falls within the specified price expectations. 7. Approval within stipulated amount – Notification of bid to winning corporation. 8. Approval above stipulated amount – For bids above the stipulated amount, bids must be forwarded to the Finance Ministry. 9. Signing of the contract – Contract must be signed in less than four months from

the issuance of letter of acceptance of bid to winning corporation. 10. Project Monitoring – Relevant agency will monitor progress to ensure that conditions of bid are met.

Regulations Governing Medical Devices:

- Advertising: There are no advertising laws which govern medical devices in Malaysia. Participation in the Malaysian Advertising Code is purely voluntary. The draft Medical Device Act calls for advertising regulation, but does not contain any specific requirements.

- Documentation: Malaysia requires all devices regarded as experimental in their home country to be internationally certified before being used in Malaysia. The forthcoming Medical Device Act is expected to be based on FDA or European certification per Global Harmonization Task Force (GHTF) guidance documents[v].

- Labeling: All medical devices in Malaysia must be labeled according to the 2005 GHTF guidelines. Basic requirements include product origin, directions for use/storage/upkeep, and safety concerns amongst others. These recommendations can be found in complete form in document GHTF/SG1/N43:2005[vi]

- Packaging: Malaysia does not currently regulate the packaging of imported medical devices; however, it is likely that packaging regulations will be incorporated in the Medical Device Act. A draft of the Medical Device Act includes instructions that a good packaging system is one which is "designed robustly and can withstand various stresses"[vii].

- Additional Regulation: The sale of Refurbished Medical Devices to public institutions is prohibited, but sales to private medical facilities are permitted. The Medical Device Act will likely require suppliers of medical devices who are not based in Malaysia to appoint a local representative.

A voluntary registration system for medical devices, MeDVER, was instituted in 2006 to facilitate a transition into a mandatory system of regulation. A mandatory registration system will likely be part of the Medical Device Act if it enters into force.

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[i] http://www.ustr.gov/assets/Document_Library/Reports_Publications/2008/2008_NTE_Report/asset_upload_file356_14651.pdf

[ii] http://216.239.59.104/search?q=cache:g0zp_oBiLZUJ:commercecan.ic.gc.ca/scdt/bizmap/interface2.nsf/vDownload/ISA_5059/%24file/X_3887275.DOC+Malaysia+tendering+process+medical+devices&hl=en&ct=clnk&cd=1&gl=us

[iii] http://eprints.utm.my/716/2/FACTORS_INFLUENCING_THE_SELECTION(2006)Maizon_Hashim.pdf

[iv] Hwei, Ooi Sue, Malaysian Business, 16 Nov. 2006.
http://findarticles.com/p/articles/mi_qn6207/is_20061116/ai_n24910536

[v] http://www.advamed.org/NR/rdonlyres/3DECC523-E60C-49D5-A03B-8D771F1D991D/0/malaysia_testimony.pdf

[vi] http://www.ghtf.org/documents/sg1/sg1final-n43.pdf

[vii] Malaysia Draft Medical Device Regulatory System in Malaysia, 6.1.3, Packaging and Labeling